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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0087]

Draft Guidance for Industry on IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides recommendations to industry on formal meetings between sponsors of investigational new drug applications (IND's) and the Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) on chemistry, manufacturing, and controls (CMC) information.

DATES: Submit written comments on the draft guidance by [*insert date 90 days after date of publication in* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/guidelines.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1488, FAX: 888–CBERFAX or 301–827–3844. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the

Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Stephen K. Moore, Center for Drug Evaluation and Research (HFD–501), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6430; or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Bldg. N29B, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information.'' This draft guidance covers three kinds of meetings held between sponsors and the agency: (1) Pre-IND, (2) end-of-phase 2, and (3) pre-new drug application or pre-biologics license application. These meetings address questions and scientific issues that arise during the course of clinical investigations, aid in the resolution of problems, and facilitate evaluation of the drug. The meetings often coincide with critical points in the drug development and/or regulatory process. This draft guidance is intended to assist in making these meetings on CMC information more efficient and effective by providing information on the: (1) Purpose, (2) meeting request (3) information package, (4) format, and (5) focus of the meeting.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on ''IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found

in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1/24/00
January 24, 2000

Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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Michael W. Bell